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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,401	01/22/2004	James Charles Bohling	A01485	9626

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,401	BOHLING ET AL.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

The current application filed on January 22, 2004 claims priority to provisional application 60/447,202 filed on February 12, 2003

Preliminary Amendment

The preliminary amendment filed January 22, 2004 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 1-12 the applicants recite a process of making a biologically active substance or a fragment of a biologically active substance, however the applicants have not shown to a person skill in the art that they had possession of the process of the invention at the time of the filing of the present application, with regards to a biologically active substance. The applicants have

provided written description for the process of making a peptide or fragments thereof (examples 1-3, pages 16-37) but not in regards to a process of determining the biological activity of the mentioned peptide, presently the applicants have not provided written description for an assay that a person of skill in the art could use to test the activity of the mentioned biologically active substance. Without an assay that allows for the testing of the activity of the mentioned biological substance it would not be possible for the applicants to show to a person skill in the art that they had possession of the invention at the time of the filing of the present application.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claims 1, 9-10** CT-AA needs to be spelled out in the first instance of use.

In **claim 2** FMOC needs to be spelled out in the first instance of use.

In **claim 8** T-20 and T-1249 need to be spelled out in the first instance of use.

In **claim 12** the phrase "low void space" is indefinite because it is not a term of art and has not been defined in the claims or the specification of the present application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Weber et al. United States Patent 5,198,531. Weber et al. teach a method of making a biologically active substance comprising reacting an activated amino acid with a trityl alcohol resin to obtain a product used for the building block for a biologically active substance. Weber et al. further teach that the activated amino acids can be selected from a variety of groups such as protected amino acid chlorides, amino acid activated esters or FMOC-amino acid chlorides and that the biologically active substances are cleaved and recycled (**present claims 1-3, 5-6 and 9-12**) (columns 3-6 and examples 1-10). Thus Weber et al. teach all the elements of **claims 1-3, 5-6 and 9-12** and these claims are anticipated under 35 USC 102(b).

Claims 1, 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ede et al. United States Patent Application Publication US 2002/0076835. Ede et al. teach using compounds such as 2-chlorotrityl alcohol in a method of peptide synthesis involving activated amino acids (**present claims 1, 3-4**) (table 1, page 6, compound/linker 14; example 19, page 10; abstract; sections 0021 and 0026, page 2 and section 0067, page 4). Thus Ede et al. teach all the elements of **claims 1, 3-4** and these claims are anticipated under 35 USC 102(b).

Claims 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kang et al. United States Patent US 6,015,881. **Claims 7 and 8** are product by process claims and even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-

process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Kang et al disclose a peptide known as T-20 (**present claims 7-8**) (table 1, No.11). Thus Kang et al. teach all the elements of **claims 7-8** and these claims are anticipated under 35 USC 102(b).

Claims 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bray et al. United States Patent US 6,469,136. **Claims 7 and 8** are product by process claims and even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Bray et al disclose a peptide known as T-1249 (**present claims 7-8**) (abstract). Thus Bray et al. teach all the elements of **claims 7-8** and these claims are anticipated under 35 USC 102(b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-8 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 14-22, and 46 of copending Application No. 10/786532. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 14-22 and 46 of Application No. 10/786532 are product by process claims drawn to T-20 and T1249. Claims 7-8 of the present application are also product by process claims drawn to T-20 and T1249. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B Mondesi
Patent Examiner
Group 1653
07-08-09

ROBERT A. WAX
PRIMARY EXAMINER